OCT - 9 2001

Thermo DMA

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510 (k) Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter: Thermo DMA, Inc.

Address: 845 Avenue G East
Arlington, Texas 76011

Contact Person: Thomas Dollar, Manager of Regulatory Affairs

The assigned 510(k) number is K012518

Product Code: CJE, Alkaline Phosphatase or isoenzymes test system

Device Name: TRACE Scientific Alkaline Phosphatase, Two-Part Liquid Assay

Device Class: II

Predicate Device: Roche Diagnostics Alkaline Phosphatase

Description and Intended Use: TRACE Scientifics' alkaline phosphatase reagents are intended for the in vitro quantitative determination of alkaline phosphatase in human serum and plasma.

Clinical Significance [1] **:**
Human alkaline Phosphatase (ALP) consists of a group of enzymes (at least five) which hydrolyze phosphates at an alkaline pH (6-8). ALP is found in practically all tissues of the body but in high concentrations in the osteoblasts of bone, liver, placenta, kidney, intestinal wall and lactating mammary glands. In adults, the ALP normally found circulating in the serum is largely derived from the liver. In children or in adolescents going through pubertal growth spurts there is an additional contribution from bone and this accounts for the higher reference interval for these groups. Pregnancy also raises the normal values of ALP.

Increased ALP (usually normal GGT) is seen in Osteomalacia and Rickets, primary hyperparathyroidism with bone involvement, Pagets disease, secondary carcinoma in bone and some cases of osteogenic sarcoma. Increased levels of ALP (usually with a raised GGT) is seen in cholestasis, hepatitis, cirrhosis, space occupying lesions and malignancy with bone or liver involvement or direct production. Low levels of ALP may be observed in conditions which cause arrested bone growth or in hypophosphatasia.

Methodology:
The TRACE ALP - AMP (IFCC) method is based on the recommendations of the International Federation of Clinical Chemistry (IFCC)[2]. This method utilizes 4-nitrophenylphosphate (4-NPP) as the substrate. Under the optimized conditions ALP present in the sample catalyses the following transphosphorylation reaction.

At the pH of the reaction 4-NPP has an intense yellow color. The reagent also contains a metal ion buffer system to ensure that optimal concentrations of zinc and magnesium are maintained. The metal ion buffer can also chelate other potentially inhibitory ions, which may be present. The reaction is monitored by measuring the rate of increase in absorbance at 405 nm, which is proportional to the activity of ALP in the serum.

Method Comparison: Comparison studies were carried out on an automated clinical chemistry analyzer(Hitachi 911). Serum samples were assayed in parallel and the results compared by the least regression method. The following statistics were obtained;

Number of Sample Pairs: 60
Range of Sample Results: 48 - 225 U/L
Mean of Results (Roche): 100 U/L
Mean of Results (TRACE Scientific): 105 U/L
Slope: 1.03
Intercept: -0.33
Correlation Coefficient: 0.9997

Precision:

Within Run

	Level 1	Level 2
Number of Data Points	40	40
Mean (U/L)	74	319
SD (U/L)	0.65	2.02
CV(%)	0.9%	0.6%

Total

	Level 1	Level 2
Number of Samples	40	40
Mean (U/L)	74	319
SD (mmol/L)	2.58	9.34
CV(%)	3.5%	2.9%

Sensitivity: The TRACE Scientific Alkaline Phosphatase reagent assay has a sensitivity of 0.4 ΔmAbs/min per U/L.

Reportable Range: Linearity studies conducted by TRACE Scientific demonstrated acceptable performance up to 2000 U/L.

Specificity: Interference studies conducted by TRACE Scientific determined the following;

1. Free Bilirubin interference - No interference from bilirubin up to 16.3 mg/dL
2. Conjugated Bilirubin - No interference from bilirubin up to 17.1 mg/dL
3. Hemoglobin interference - No interference from hemoglobin up to 790 mg/dL
4. Lipemia: When measured bichromatically, no interference from lipemia, measured as triglycerides, up to 2000 mg/dL.

Reference Ranges[3]: At 37° C

Age Group	Sex	Range
20 - 50	Males	53 - 128 U/L
20 - 50	Females	42 - 98 U/L
> 60	Males	56 - 119 U/L
> 60	Females	53 - 141 U/L

Conclusion: Analysis of the comparative measurements presented in the 510(k) submission for this reagent, together with linearity and precision data collected in data presented demonstrates the TRACE Alkaline Phosphatase assay is safe and effective. No significant differences exist between the results obtained on samples analyzed utilizing the TRACE Scientific Alkaline Phosphatase when compared to those obtained when utilizing the predicate device in these studies.

References:

1. Zilva JF, Pannall PR, "Plasma Enzymes in Diagnosis" in Clinical Diagnosis and Treatment. Lloyd London 1979:Chap 15 343.
2. IFCC method for the measurement of ALP J Clin Chem Clin Biochem 1983: 21:731-48.
3. Tietz Textbook of Clinical Chemistry, Second Edition, WB Saunders 1994;830-843.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 2001

Mr. Thomas Dollar
Manager of Regulatory Affairs
Thermo DMA
845 Avenue G East
Arlington, TX 76011-7709

Re: k012518
Trade/Device Name: TRACE Scientific Alkaline Phosphatase Assay
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Dollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012518

Device Name: TRACE Scientific Alkaline Phosphatase Assay

Indications For Use: This reagent is intended for the in vitro quantitative determination of Alkaline Phosphatase in human serum and plasma. Measurements of Alkaline Phosphatase or its isoenzymes are used as in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012518

Prescription Use ✔ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)